

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION

)
)
) MDL NO. 1456
) Civil Action No. 01-12257-PBS
)

THIS DOCUMENT RELATES TO:

) Judge Patti B. Saris
)

The City of New York v. Abbott Laboratories, Inc., et al.
(S.D.N.Y. No. 04-CV-06054)

County of Albany v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00425)

County of Allegany v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06231)

County of Broome v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00456)

County of Cattaraugus v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06242)

County of Cayuga v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00423)

County of Chautauqua v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06204)

County of Chemung v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06744)

County of Chenango v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00354)

County of Columbia v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00867)

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**ANSWER AND AFFIRMATIVE DEFENSES OF FUJISAWA HEALTHCARE, INC.
AND FUJISAWA USA, INC. TO THE
REVISED FIRST AMENDED CONSOLIDATED COMPLAINT**

<i>County of Cortland v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00881))
<i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 05-CV-06458))
<i>County of Essex County v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00878))
<i>County of Fulton v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00519))
<i>County of Genesee v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06206))
<i>County of Greene v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00474))
<i>County of Herkimer v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00415))
<i>County of Jefferson v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00715))
<i>County of Lewis v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00839))
<i>County of Madison v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00714))
<i>County of Monroe v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06148))
<i>County of Nassau v. Abbott Laboratories, Inc., et al.</i>)
(E.D.N.Y. No. 04-CV-5126))
<i>County of Niagara v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06296))
<i>County of Oneida v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00489))
<i>County of Onondaga v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00088))
<i>County of Ontario v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06373))
<i>County of Orange v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 07-CV-2777))
<i>County of Orleans v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06371))
<i>County of Putnam v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 05-CV-04740))

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<i>County of Rensselaer v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00422))
<i>County of Rockland v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 03-CV-7055))
<i>County of Saratoga v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00478))
<i>County of Schuyler v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06387))
<i>County of Seneca v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06370))
<i>County of St. Lawrence v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00479))
<i>County of Steuben v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06223))
<i>County of Suffolk v. Abbott Laboratories, Inc., et al.</i>)
(E.D.N.Y. No. CV-03-229))
<i>County of Tompkins v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00397))
<i>County of Ulster v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 06-CV-0123))
<i>County of Warren v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00468))
<i>County of Washington v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00408))
<i>County of Wayne v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06138))
<i>County of Westchester v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 03-CV-6178))
<i>County of Wyoming v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 03-CV-6379))
AND)
<i>County of Yates v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06172))

Defendants Fujisawa Healthcare, Inc. and Fujisawa USA, Inc. (collectively, “Fujisawa”), by and through their attorneys, hereby state as an Answer and Affirmative Defenses to the Revised First Amended Consolidated Complaint, dated October 5, 2001, as follows:

PRELIMINARY STATEMENT

The First Amended Consolidated Complaint (the “Complaint”) improperly refers to Fujisawa, other defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Fujisawa. This is insufficient to apprise Fujisawa (let alone each separate entity) of the allegations asserted against it. Fujisawa has nevertheless attempted to respond to Plaintiffs’ allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Fujisawa is generally without knowledge or information sufficient to form a belief as to the truth of those allegations. Fujisawa states that it is answering Plaintiffs’ allegations solely on behalf of itself, even when Plaintiffs’ allegations refer to alleged conduct by Fujisawa and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Fujisawa’s failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Fujisawa’s reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Fujisawa denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations,

implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, Fujisawa specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Fujisawa has included in this Answer and Affirmative Defenses the caption used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, that caption.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

SPECIFIC RESPONSES

To the extent that the unnumbered paragraph immediately following the Table of Contents (the “Complaint’s Introductory Paragraph”) makes allegations against Fujisawa, Fujisawa denies them, except admits that the City of New York and certain New York Counties (collectively, the “Counties”) have made allegations against a number of defendants, including Fujisawa, as set forth in the Complaint. To the extent that the Complaint’s Introductory Paragraph states legal conclusions, no response is required. To the extent the allegations of the Complaint’s Introductory Paragraph are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations.

1. Fujisawa admits that the Counties seek to bring this action as alleged in Paragraph 1 of the Complaint, but Fujisawa denies there is any basis for them to do so and denies that they are entitled to any relief. Fujisawa also admits that Exhibit B to the Complaint purport to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiffs with respect to any such NDCs. To the extent the remaining allegations in Paragraph 1 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has been involved in

“fraudulent and misleading schemes” or that the New York State Medicaid Program has been “overcharge[d]” for prescription drugs. To the extent the remaining allegations in Paragraph 1 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

2. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 or the exhibit referenced therein. To the extent the allegations in Paragraph 2 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

3. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 or its footnote, except admits that it pays Medicaid rebates to the State of New York and that such rebates lower the price New York Medicaid pays for Fujisawa’s prescription drugs. To the extent the allegations in Paragraph 3 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

4. To the extent the allegations in Paragraph 4 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it was involved in “fraudulent schemes,” the “manipulation of the Medicaid program” or the “intentional fraudulent inflation” of wholesale prices, or that the Counties’ Medicaid Programs were “overcharge[d].” To the extent the allegations in Paragraph 4 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

5. To the extent the allegations in Paragraph 5 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Fujisawa otherwise

denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. To the extent the allegations in Paragraph 6 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Fujisawa otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 or its footnote, except Fujisawa denies that it “actively encourage[s] physicians to write DAW in order to secure AWP-based reimbursement for pharmacies.”

7. To the extent the allegations in Paragraph 7 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Fujisawa otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7.

8. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8.

9. To the extent the allegations in Paragraph 9 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it “control[s] and unlawfully inflates[s]” average wholesale prices (“AWPs”) or federal upper limits (“FULs”). To the extent the allegations in Paragraph 9 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

10. To the extent the allegations in Paragraph 10 are directed at Fujisawa, Fujisawa denies them, except Fujisawa admits that it has provided the wholesale list price of its drugs to

certain industry pricing compendia and that publishers apply their own markups to the list prices. Fujisawa specifically denies that it “set[s] AWP.” To the extent the allegations in Paragraph 10 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

11. To the extent the allegations in Paragraph 11 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 11 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

12. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “report[ed] a false and inflated WAC or WAC equivalent” to industry pricing compendia. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

13. To the extent the allegations in Paragraph 13 are directed at Fujisawa, Fujisawa denies them, except Fujisawa admits that CMS has established FULs for certain drugs. Fujisawa specifically denies that it “control[s] the FUL.” To the extent the allegations in Paragraph 13 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 13 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

14. To the extent the allegations in Paragraph 14 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 14 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

15. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

16-17. To the extent the allegations in Paragraphs 16-17 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it “submit[s] false and inflated price information to the publishing compendia.” Fujisawa further denies the characterization of “spread” in Paragraphs 16-17. To the extent the allegations in Paragraphs 16-17 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

18-19. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 18-19.

20. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20. To the extent the allegations in Paragraph 20 refer to a Wall Street Journal article, the article speaks for itself, and any characterizations thereof are denied.

21. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 or the exhibit referenced therein.

22. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22.

23. To the extent the allegations in Paragraph 23 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “secretly polluted the entire reimbursement system with false and inflated prices.” To the extent the allegations in Paragraph 23 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

24. To the extent the allegations in Paragraph 24 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “cause[d] false and inflated published reimbursement prices to issue.” Fujisawa further denies the characterization of “spread” in Paragraph 24. To the extent the allegations in Paragraph 24 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

25. To the extent the allegations in Paragraph 25 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “create[d], inflate[d], manipulate[d] and market[ed] the spread for both brand name and generic drugs.” To the extent the allegations in Paragraph 25 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

26. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26. To the extent the allegations in Paragraph 26 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

27. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27. To the extent the allegations in Paragraph 27 refer to the

transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

28. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has engaged in “intentional AWP inflation” or “fraud.” Fujisawa further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

29. To the extent the allegations in Paragraph 29 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “reported or caused to be reported [] false and inflated” WACs or engaged in any “unlawful and undisclosed manipulation of the price reporting system.” To the extent the allegations in Paragraph 29 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

30. To the extent the allegations in Paragraph 30 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has engaged in any “pricing misconduct.” To the extent the allegations in Paragraph 30 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

31. To the extent the allegations in Paragraph 31 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

Fujisawa otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 or its footnote, except Fujisawa admits that it pays Medicaid rebates as required by law.

32. To the extent the allegations in Paragraph 32 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 32 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

33. To the extent the allegations in Paragraph 33 or its footnote are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “abused” any Medicaid statute. To the extent the allegations in Paragraph 33 or its footnote are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 33 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

34. To the extent the allegations in Paragraph 34 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 34 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 34 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

35. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35.

36. To the extent the allegations in Paragraph 36 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them, except Fujisawa admits that it settled without an

admission of liability a government investigation related to drug pricing. To the extent the allegations in Paragraph 36 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

37. Fujisawa admits that the Counties seeks the relief listed in Paragraph 37, but Fujisawa denies there is any basis for them to do so and denies that they are entitled to any relief. To the extent the remaining allegations in Paragraph 37 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has been involved in any “fraudulent and illegal manipulation of drug prices.” To the extent the remaining allegations in Paragraph 37 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

38. Fujisawa admits that the Counties seek to bring this action as alleged in Paragraph 38, but Fujisawa denies there is any basis for them to do so and denies that they are entitled to any relief.

39-40. Paragraphs 39-40 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, Fujisawa denies the allegations in Paragraphs 39-40, except admits that each of the captioned matters has been transferred to this Court by the Judicial Panel on Multi District Litigation pursuant to 28 U.S.C. 1407.

41-42A. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 41-42 and 42A. To the extent the allegations in Paragraphs 41-42 and 42A refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

43. Fujisawa denies the allegations in Paragraph 43 and its footnote, and refers to Case Management Order No. 33, dated September 14, 2007, ¶¶ 1, 3 for which plaintiffs are suing which defendants.

44. To the extent the allegations in Paragraph 44 are directed at Fujisawa, Fujisawa denies them, except Fujisawa admits that it manufactures and sells prescription drugs and that it transacts business in the State and City of New York. Fujisawa specifically denies that it “manufactures, markets and sells prescription drugs with false and inflated wholesale prices.” To the extent the allegations in Paragraph 44 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

45-62. The allegations in Paragraphs 45-62 are directed to other defendants and require no response from Fujisawa. To the extent a response is deemed to be required, Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 45-62.

63. Fujisawa admits that Fujisawa Healthcare, Inc. was a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois and that it manufactured and sold pharmaceuticals. Fujisawa admits that Fujisawa USA, Inc. was a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois and that it manufactured and sold pharmaceuticals. Fujisawa denies the remaining allegations in Paragraph 63.

64-84. The allegations in Paragraphs 64-84 are directed to other defendants and require no response from Fujisawa. To the extent a response is deemed to be required, Fujisawa denies

knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64-84.

85-88. The allegations in Paragraphs 85-88 are directed to unknown defendants and require no response from Fujisawa. To the extent a response is deemed to be required, Fujisawa denies that it was involved any conspiracy related to drug pricing with either named or unknown defendants. Fujisawa also denies that it has engaged in any “wrongful acts” related to drug pricing.

89. With respect to the allegations in Paragraph 89, Fujisawa admits that Medicaid was established by Title XIX of the Social Security Act. Fujisawa further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

90. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90, except Fujisawa admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 90 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

91-99. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 91-99 or their footnotes. To the extent the allegations in Paragraphs 91-99 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

100. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 100, except admits that national drug codes are assigned to prescription drugs and that the FOA assigns such codes.

101-111. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 101-111 or their footnotes. To the extent the allegations in Paragraphs 101-111 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

112. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 112, except admits that pricing compendia such as Blue Book publish AWP and FULs, and denies that Fujisawa has any control over such prices.

113. To the extent the allegations in Paragraph 113 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it has “fraudulently conceal[ed]” the “true prices” of its drugs by “claiming they are proprietary trade secrets.” To the extent the allegations in Paragraph 113 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 113 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

114-115. To the extent the allegations in Paragraphs 114-115 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it reports “reimbursement prices . . . to the publishing compendia” or that it has engaged in the “purposeful manipulation of reimbursement prices generally, and AWP in particular.” Fujisawa further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally

understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 114-115 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 114-115 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

116-123. With respect to the allegations in Paragraphs 116-123 and their footnotes, Fujisawa admits that the Medicaid statute includes a rebate provision, that it has entered into a rebate agreement with the Secretary of Health and Human Services, and that rebates help reduce state Medicaid drug expenditures. Fujisawa further states that the rebate provision speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 116-123 or their footnotes refer to additional statutes, regulations or congressional reports, those sources also speak for themselves, and any characterizations thereof are also denied.

124-125. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 124-125. To the extent the allegations in Paragraphs 124-125 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Fujisawa denies that the Counties are intended third-party beneficiaries of Medicaid rebate agreements.

126. With respect to the allegations in Paragraph 126, Fujisawa admits that drug manufacturers report Best Prices and AMPs to HHS. To the extent the allegations in Paragraph 126 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

127-130. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 127-130, except admits that it reports Medicaid information to HHS and pays rebates to States. To the extent the allegations in Paragraphs 127-130 refer to statutes, regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied.

131. To the extent the allegations in Paragraph 131 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 131 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 131 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

132. To the extent the allegations in Paragraph 132 are directed at Fujisawa, Fujisawa admits that it has executed a rebate agreement with HHS. Fujisawa further states that the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraph 132 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 132 refer to the Model Rebate Agreement, that document also speaks for itself, and any characterizations thereof are also denied.

133-136. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 133-136. To the extent the allegations in Paragraphs 133-136 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

137-143. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 137-143, except Fujisawa denies that the Counties are Medicaid payors or intended third-party beneficiaries of Medicaid rebate agreements. To the extent the allegations in Paragraphs 137-143 refer to statutes, regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied.

144. To the extent the allegations in Paragraph 144 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it “intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and inflated.” Fujisawa further denies the characterization of “spread” in Paragraph 144. To the extent the allegations in Paragraph 144 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

145-149. With respect to the allegations in Paragraphs 145-149, Fujisawa admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it “routinely submitted fraudulent prices” to pricing compendia. Fujisawa further denies the characterization of “spread” in Paragraphs 145-149 and Exhibit B. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

150-153. To the extent the allegations in Paragraphs 150-153 are directed at Fujisawa, Fujisawa denies them. Fujisawa further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 150-153 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

154. Paragraph 154 purports to contain a statement from HHS OIG, but Fujisawa denies knowledge or information sufficient to form a belief as to its accuracy because the source thereof is not provided. To the extent the source of the statement is provided, the source speaks for itself, and any characterizations thereof are denied.

155-158. To the extent the allegations in Paragraphs 155-158 are directed at Fujisawa, Fujisawa denies them. Fujisawa further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 155-158 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

159-165. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 159-165, except Fujisawa admits that PBMs are involved in administering and managing prescription drug benefit programs and that certain PBMs also operate mail order pharmacies. To the extent the allegations in Paragraphs 159-165

refer to articles or reports, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at Fujisawa, Fujisawa denies them. Fujisawa specifically denies that it “control[s] the published reimbursement prices.” To the extent the allegations in Paragraph 166 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

167. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167.

168-172. To the extent the allegations in Paragraphs 168-172 are directed at Fujisawa, Fujisawa denies them, except Fujisawa that it has executed a rebate agreement with HHS. Fujisawa further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Fujisawa. In any event, the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 168-172 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 168-172 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

173-176/ To the extent the allegations in Paragraphs 173-176 are directed at Fujisawa, Fujisawa denies them, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Fujisawa. To the extent the allegations in Paragraphs 173-176 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in

Paragraphs 173-176 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

177. To the extent the allegations in Paragraph 177 are directed at Fujisawa, Fujisawa denies them, except admits that Fujisawa has settled certain government investigations of pharmaceutical pricing without an admission of liability. To the extent the allegations in Paragraph 177 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

178-194. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 178-194 or their footnotes refer to reports, articles, letters, congressional hearing transcripts, or other documents, those sources speak for themselves, and any characterizations thereof are denied.

195. To the extent the allegations in Paragraph 195 are directed at Fujisawa, Fujisawa denies them, except Fujisawa admits that its contracts with purchasers sometimes included discounts. To the extent the allegations in Paragraph 195 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

196. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

197-468. The allegations in Paragraphs 197-468 are directed to other defendants and require no response from Fujisawa. To the extent a response is deemed to be required, Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 197-468.

469. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 469 or its footnote or the exhibit referenced therein, except Fujisawa denies that it engaged in any “fraud,” and states that Exhibits A and B to the Complaint have changed since the filing of the Complaint.

470. Fujisawa denies the allegations in Paragraph 470 and the exhibit referenced therein, and states that Exhibits A and B to the Complaint have changed since the filing of the Complaint.

471. Fujisawa denies the allegations in Paragraph 471. To the extent the allegations in Paragraph 471 refer to letters from Representative Stark, the letters speak for themselves, and any characterizations thereof are denied.

472. Fujisawa denies the allegations in Paragraph 472, except admits that it has been the subject of investigations by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Montana, Texas and California.

473-476. Fujisawa denies the allegations in Paragraphs 473-476.

477-769. The allegations in Paragraphs 477-769 are directed to other defendants and require no response from Fujisawa. To the extent a response is deemed to be required, Fujisawa

denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 477-769.

770-772. To the extent the allegations in Paragraphs 770-772 are directed at Fujisawa, Fujisawa denies them, except Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegation that the Counties' Medicaid programs "spent over \$20 billion for defendants' drugs from 1992 – 2005." Fujisawa specifically denies that it was involved in any "false price reporting scheme" or "misconduct," or that it has been "unjustly enriched." To the extent the allegations in Paragraphs 770-772 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

773-790. To the extent the allegations in Paragraphs 773-790 are directed at Fujisawa, Fujisawa denies them. Fujisawa further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 773-790 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 786 refer to The Pink Sheet, that document speaks for itself, and any characterizations thereof are denied.

COUNT I
VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO
COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)

791. In response to Paragraph 791, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 790.

792-807. To the extent the allegations in Paragraphs 792-807 are directed at Fujisawa, Fujisawa states that the Court has dismissed them. To the extent that a response is still required, Fujisawa denies the allegations as to itself. To the extent the allegations in Paragraphs 792-807 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

COUNT II

VIOLATION OF N.Y. SOCIAL SERVICES LAW 367-a(7)(d) (FAILURE TO COMPLY WITH STATE MEDICAID REBATE PROVISION)

801. In response to Paragraph 801, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 800.

802-807. To the extent the allegations in Paragraphs 802-807 are directed at Fujisawa, Fujisawa states that the Court has dismissed them. To the extent that a response is still required, Fujisawa denies the allegations as to itself. To the extent the allegations in Paragraphs 802-807 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

COUNT III

VIOLATION OF NEW YORK SOCIAL SERVICES LAW 145-b (OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS)

808. In response to Paragraph 808, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 807.

809. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 809. To the extent the allegations in Paragraph 809 refer to

statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

810-813. To the extent the allegations in Paragraphs 810-813 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 810-813 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 810-813 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 810-813 contain legal conclusions, no response is required.

COUNT IV

VIOLATION OF NEW DEPARTMENT OF HEALTH REGULATIONS 18 N.Y.C.R.R. 512.2(b)(4) and (5)

814. In response to Paragraph 814, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 813.

815-817. To the extent the allegations in Paragraphs 815-817 are directed at Fujisawa, Fujisawa states that the Court has dismissed them. To the extent that a response is still required, Fujisawa denies the allegations as to itself. To the extent the allegations in Paragraphs 814-817 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

COUNT V

BREACH OF CONTRACT

818. In response to Paragraph 818, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 817.

819-830. To the extent the allegations in Paragraphs 819-830 are directed at Fujisawa, Fujisawa states that the Court has dismissed them. To the extent that a response is still required, Fujisawa denies the allegations as to itself. To the extent the allegations in Paragraphs 819-830 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

COUNT VI

UNFAIR TRADE PRACTICES (Violations of N.Y. Gen. Bus. Law 349 *et seq.*)

831. In response to Paragraph 831, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 830.

832-835. To the extent the allegations in Paragraphs 832-835 and the exhibits referenced therein are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 832-835 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 832-835 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

836-837. To the extent the allegations in Paragraphs 836-837 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 836-837 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 836-837 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

838-839. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto contain legal conclusions, no response is required.

COUNT VII

FRAUD

840. In response to Paragraph 840, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 839.

841-843. To the extent the allegations in Paragraphs 841-843 and the exhibits referenced therein are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 841-843 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth.

844. Fujisawa denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 844. To the extent the allegations in Paragraph 844 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

845. To the extent the allegations in Paragraph 845 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraph 845 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 845 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 845 contain legal conclusions, no response is required.

COUNT VIII
UNJUST ENRICHMENT

846. In response to Paragraph 846, Fujisawa repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 845.

847-849. To the extent the allegations in Paragraphs 847-849 are directed at Fujisawa, Fujisawa denies them. To the extent the allegations in Paragraphs 847-849 are directed at parties other than Fujisawa, Fujisawa denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 847-849 contain legal conclusions, no response is required.

850-858. Fujisawa denies that the Counties are entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 850-858 of the Complaint.

WHEREFORE, Fujisawa demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

AFFIRMATIVE DEFENSES

Fujisawa reasserts and incorporates herein by reference the assertions of paragraphs 1 through 111 hereof.

First Affirmative Defense

Plaintiff fails to state a claim against Fujisawa upon which relief may be granted.

Second Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because they did not rely on any alleged misrepresentations or fraud by Fujisawa. Plaintiffs knew that providers could obtain Fujisawa drugs at prices below AWP prior to the relevant time period stated in the Complaint.

Third Affirmative Defense

Plaintiffs' claim is barred, in whole or in part, by the political question and separation of powers doctrines.

Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the filed rate doctrine.

Fifth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the state action doctrine.

Sixth Affirmative Defense

To the extent Plaintiffs or the State of New York obtain recovery in any other case predicated on the same factual allegations, Plaintiffs are barred from seeking recovery against Fujisawa based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

Seventh Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Fujisawa in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Eighth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiffs' claims.

Ninth Affirmative Defense

Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Tenth Affirmative Defense

Plaintiffs' claims against Fujisawa are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

Eleventh Affirmative Defense

Plaintiffs fail to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Fujisawa contained in the Complaint.

Twelfth Affirmative Defense

Any and all actions taken by Fujisawa with respect to any of the matters alleged in the

Complaint were taken in good faith and in accordance with established industry practice.

Thirteenth Affirmative Defense

Fujisawa's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs.

Fourteenth Affirmative Defense

Fujisawa denies that Plaintiffs have valid consumer protection claims against Fujisawa under New York's Unfair Trade Practices Act. However, if such claims are found to exist, Fujisawa pleads all available defenses under the Act.

Fifteenth Affirmative Defense

To the extent that Plaintiffs attempt to seek equitable relief against Fujisawa, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

Sixteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Seventeenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs have received and paid for medicines manufactured, marketed and sold by Fujisawa after the filing of the complaint of Suffolk County.

Eighteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

Nineteenth Affirmative Defense

Plaintiffs' claims against Fujisawa are barred, in whole or in part, due to their failure to join indispensable parties.

Twentieth Affirmative Defense

Plaintiffs' claims against Fujisawa are barred, in whole or in part, because Plaintiffs have not suffered damages as a result of the matters alleged in the Complaint.

Twenty-First Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to mitigate damages, and that failure to mitigate damages should proportionately reduce Plaintiffs' recovery and the allocation of any fault, if any exists, attributable to Fujisawa.

Twenty-Second Affirmative Defense

Fujisawa is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs, with respect to the same alleged injuries.

Twenty-Third Affirmative Defense

To the extent punitive damages are sought, Plaintiffs' punitive damages claims against Fujisawa are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against FUJISAWA.

Twenty-Fourth Affirmative Defense

To the extent punitive damages are sought, Plaintiffs' damages claims against Fujisawa cannot be sustained because an award of punitive damages would violate the United States Constitution, Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII and the Due Process Clause of the Fourteenth Amendment, U.S. Const. amend. XIV, § 1 and the

analogous provisions contained in the Constitutions of the State of New York and any other States whose laws are or become relevant in the course of this lawsuit.

Twenty-Fifth Affirmative Defense

Fujisawa adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Twenty-Sixth Affirmative Defense

Fujisawa hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense.

Respectfully Submitted,

REED SMITH LLP

By: /s/ Andrew L. Hurst

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Attorneys for Defendants Fujisawa
USA, Inc. and Fujisawa Healthcare,
Inc.

Dated: October ___, 2007

CERTIFICATE OF SERVICE

I certify that a true and correct copy of Fujisawa Healthcare, Inc.'s and Fujisawa USA, Inc.'s Answer To Plaintiffs' Revised Amended Consolidated Complaint was delivered to all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending, on the 26th day of October, 2007, a copy to LexisNexis File & Serve for posting and notification to all parties.

_____/s/ Andrew L. Hurst_____
Andrew L. Hurst